

May 2, 2004

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Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Dear Sir/Madam:

## Subject: Dietary supplement label notification

The following notification is being filed in accordance with 21 C.F.R. § 101.93(a) on behalf of Nature-Recommended, LLC, P.O. Box 8815, Reston, VA 20195, which is the distributor of the dietary supplement that bears the statements identified in this notification.

The text of the statements that are being made on the label is: "Alleviates Hot Flashes" and "Maintains Strong Bones".

The name (including brand name) of the dietary supplement that is the subject of the statements is "Menopause Relief Dietary Supplement".

The label at issue includes the following disclaimer, in accordance with applicable regulations: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

I, Brigid Gray-McNeish, am authorized to certify this Notification on behalf of Nature-Recommended, LLC. I hereby certify that the information contained in this notice is complete and accurate, and that Nature-Recommended, LLC has substantiation that the statement is truthful and not misleading.

Sincerely,

**Brigid Gray-McNeish** 

Member

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